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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,721	02/12/2001	H. Michael Shepard	126745200402	5394

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EXAMINER

CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
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1623

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/782,721</b>	Applicant(s) <b>Shepard et al.</b>
	Examiner <b>L. E. Crane</b>	Group Art Unit <b>1623</b>

**- THE MAILING DATE of this communication appears on the cover sheet beneath the correspondence address -**

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE --3-- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

## Status

Responsive to communication(s) filed on 06/07/02 (Seq. Discl.), 06/12/02 (amdt B & IDS#3) & 07/01/02(IDS#4).

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

Claims —56-89— are pending in the application. Claim -1- has been cancelled.  
Of the above claim(s) —1— is/are withdrawn from consideration.

Claim(s) —1— is/are allowed.

Claims —56-89— are rejected.

Claim(s) —1— is/are objected to.

Claim(s) —1— are subject to restriction or election requirement.

## Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawings, filed on -05/15/01- are  approved  disapproved.

The drawing(s) filed on -1- is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119(a)-(d)

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

All  Some <sup>\*</sup>  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) -1-.

received in the national stage application from the International Bureau (PCT Rule 17.2(a)).

<sup>\*</sup> Certified copies not received: -1-.

## Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). -11, 13-  Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948  Other: -1-

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Claim 1 has been cancelled, claims 56-59, 61-62, 64-65, 67-70 and 86-88 have been amended, and no new claims have been added as per the amendment filed June 12, 2002. The submitted ECRF has been reviewed, found acceptable, and entered into the PTO database. Two 5 Information Disclosure Statements (IDS's) filed June 12, 2002 and July 1, 2002 have been received and made of record.

Claims 56-89 remain in the case.

Claim 85 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 85 reference is made to assays using compounds which have been disclosed generically or subgenerically. This reference to compounds is excessively broad in light of the disclosure wherein only selected compounds have been tested.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

Inspection of the disclosure at page 60 provides only a prospective 20 disclosure of the claimed assay method. Clearly one of ordinary skill would have to figure out the details of how to practice the claimed method in view of the nearly nonexistent guidance provided by the very brief disclosure found at page 60 of the specification. It is well known and established that "law requires that disclosure in an application shall 25 inform those skilled in the art how to use appellant's alleged discovery,

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not how to find out how to use it for themselves." *In re Gardner et al.*, 166 USPQ 138 (CCPA 1970).

5       Applicant's response indicates that the rejection of claim 85 "... is discussed below." However, no further specific reference is made to the instant claim in the remainder of the response. And following careful review of the disclosure, examiner finds no examples or other guidance permitting the ordinary practitioner to practice the claimed assay without undue experimentation. For the above noted reasons, the instant grounds of rejection have been maintained.

10       Claims 56-61, 84 and 86-89 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

15       In claims 56-61, 81-84 and 86-89 reference is made to methods of treatment using compounds which have been disclosed generically or subgenerically. This reference to compounds is excessively broad in light of the disclosure wherein only selected compounds have been tested and as to the types of cancer which can be treated; no data is 20 provided to show effective treatment of liver cancer.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

25       Applicant argues that the disclosure "sets forth numerous working and prophetic examples that enable the full scope of the claims" without making specific reference to the actual number of medicinally directed examples (only 3 active ingredients were tested against four varieties of cancer in vitro). Additionally, said examples do not fit within the

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generic definition of compounds wherein the substituent R<sub>1</sub> is as defined in claim 61, which definition is apparently missing a (-CH<sub>2</sub>-) group (compare with the second structure in claim 58) the absence of which renders the definitions in part structurally incorrect (e.g. primary vinyl hydroxyl groups are also known as aldehydes). Yet applicant apparently argues that this limited test regimen is adequate for one or ordinary skill to extrapolate to all "hyperproliferative" cell type diseases including everything from psoriasis to cancers of the liver and the pancreas.

Examiner respectfully disagrees, noting that the applicant's in *Ex parte Balzarini* (21, USPQ 2d 1892, 1894 (BPAI, 1991)) attempted to assert that compounds that had some of the structural features of AZT should be medicinally effective in treating HIV without any showing of test data. Applicant has made a similar argument, and like the applicant's in *Balzarini*, instant applicant has not provided sufficient guidance to permit the ordinary practitioner to have confidence that there is a well established basis for making an extrapolation to the treatment of all of the disease conditions which may be conceivably included within the scope of the term "inhibiting the proliferation of a hyperproliferative cell," or that a substantial number of the compounds alleged to be active are in fact active against any neoplastic disease condition. Examiner respectfully disagrees that the PTO must accept applicant's specification without question, particularly in the case of medicinal treatments, and more particularly when said specification is accompanied by claims directed to a generically effective treatment of all neoplastic disease conditions. See the MPEP at 2107.03 (p. 2100-44 et seq, in the August, 2001 revision).

For these reasons the instant grounds of rejection have been maintained.

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In claims 62-89 reference is made to compounds which have been claimed generically and subgenerically. This reference to compounds is excessively broad in light of the disclosure wherein only selected compounds have been actually synthesized.

5       Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

10      Applicant's generic claims are simply too broad when only a very small number of examples have been synthesized and tested. It is well known and established that "law requires that disclosure in an application shall inform those skilled in the art how to use appellant's alleged discovery, not how to find out how to use it for themselves," *In re Gardner et al.*, 166 USPQ 138 (CCPA 1970). In addition the instant claims have not met the written description standard of Regents of the University of California v. Eli Lilly (119F.3d 1559 at 1568; 43 USPQ2d 1398 at 1406 (Fed. Cir 1997)) which MPEP §2163 at page 2100-162, column 1, quotes as follows: "A definition by function alone 'does not suffice' to describe a coding sequence 'because it is only an indication of what the gene does, rather than what it is.'" Applicant continues to rely on generic functional terminology including "masked phosphate group" 20 wherein the disclosure definition thereof does not overcome the functionality of the noted term.

25      Claims 1 and 56-59, 61-63, 65, 72 and 81-87 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

      In claim 57 at line 1, the term "characterized by" is indefinite because the meaning implied by the noted term is not judicially

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established. Additionally the following term "hyperproliferative cells" are indefinite for failure to specify the particular disease being referred to; is it cancer and if so which cancer or cancers? Or alternatively, is the disease some variety of psoriasis? See also claims 56, 58, 81-84, 86 5 ("pathological cell" fails to define the disease) and 87.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

Applicant has failed to respond to the first sentence of the instant rejection.

10      Applicant argues that the term "hyperproliferative cells" is well defined, and cited pages from a dictionary in support thereof. However, only one dictionary page (p. 1001) has been provided and therefore the instant response is incomplete. Assuming the dictionary quotations are correct, applicant's claim may be read to read on administration of one 15 of the instant compounds as abortifacients intended to be administered to kill a fetus, which necessarily must be a bundle of hyperproliferative cells, particularly in the early stages of its growth. Or alternatively, the noted term reads on preventing the healing process following wounding of a host, wherein said process, to protect the life of the host, must necessarily provide rapidly dividing cells to generate a scab and then to 20 regenerate the damaged tissues. Or alternatively, the method reads on the killing of bone marrow stem cells, a process not provided for by the instant disclosure. Or alternatively, the instant methods reads on prevention of the regeneration of a host's liver following partial excision 25 thereof to provide liver tissue for a transplant. Etc., etc., etc.

In claim 58 the terms "sugar," "thio sugar," "carbocyclic," "acyclic analogs and derivatives of a sugar," "a thio-sugar or a carbocyclic,"

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5 "derivatives," "analogs" are indefinite for failure to provide the structural details to the chemical species being referred to. In addition, the term "carbocyclic" is unnecessarily repeated and also is not further provided with an upper size limit; the terms "sugar" and "thiosugar" are compounds (-- sugar group --?); and, the terms "analogs" and "derivatives" are open ended (no metes and bounds or other limits on the definition).

10 Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

15 Comparison with the previous version of the instant claim indicates that the amended version has been inaccurately presented. Applicant is respectfully requested to accurately represent both deletion and addition amendments in the marked-up version.

20 15 Regents of the University of California v. Eli Lilly (119F.3d 1559 at 1568; 43 USPQ2d 1398 at 1406 (Fed. Cir 1997)) is quoted by the MPEP §2163 at page 2100-162, column 1, as follows: "A definition by function alone 'does not suffice' to describe a coding sequence 'because it is only an indication of what the gene does, rather than what it is.'" Applicant continues to rely on generic and functional terminology including the terms listed above wherein the disclosure definition thereof does not overcome the noted generic functionality of the listed term. Complete and detailed structural representations are respectfully requested.

25 Claim 59 is indefinite for failure to provide the structural details for the chemical species ("masked phosphoryl moiety" and "phosphoramidatyl moiety") being referred to.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

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Regents of the University of California v. Eli Lilly (119F.3d 1559 at 1568; 43 USPQ2d 1398 at 1406 (Fed. Cir 1997)) is quoted by the MPEP §2163 at page 2100-162, column 1, as follows: "A definition by function alone 'does not suffice' to describe a coding sequence 'because it is only an indication of what the gene does, rather than what it is.'" Applicant continues to rely on generic and functional terminology including the terms listed above wherein the disclosure definition thereof does not overcome the noted generic functionality of the listed term. Complete and detailed structural representations are respectfully requested.

In claim 62 at lines 10-11, the term "aromatic hydrocarbyl" is incomplete because it is not clear whether applicant is referring to an -- aromatic hydrocarbyl group -- or a compound. The same criticism also applies to the term "a heteroaromatic." Also said terms both lack an upper size limit and therefore render the instant compound indefinite for failure to provide adequately defined metes and bounds. Also, the term "heteroaromatic" is incompletely defined for failure to define the identity or limits on the proportion of the heteroatom or heteroatoms present.

Applicant's arguments with respect to claims 1 and 56-89 have been considered but are moot in view of the new grounds of rejection.

Claims 63, 72 and 85 lack terminal punctuation.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

Applicant has not responded to this grounds of rejection with the appropriate amendments.

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The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **56-61, 81-84 and 86-89** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim **1-12** of copending allowed Application No. **09/130,839**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

Applicant has acknowledged but has deferred response to this grounds of rejection.

5       Claim 62-80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-39 of U. S. Patent No. 6,339,151. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are 10 directed to substantially overlapping subject matter.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

Applicant has acknowledged but has deferred response to this grounds of rejection.

15       Claims 56-84 and 86-89 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U. S. Patent No. 6,245,750. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of treatment and the alleged active ingredients are 20 directed to substantially overlapping subject matter.

Applicant's arguments filed June 12, 2002 have been fully considered but they are not persuasive.

Applicant has acknowledged but has deferred response to this grounds of rejection.

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Claims 56-84 and 86-89 of this application conflict with claims of Application No. 09/130,839. 37 C.F.R. §1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

10 The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

“A person shall be entitled to a patent unless -

15 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.”

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.”

20 Claims 56-84 and 86-89 are rejected under 35 U.S.C. §102(b) as being anticipated by Robugen ‘169 (PTO-1449 ref. B18).

Applicant is referred to claims 1 and 3 of the noted reference wherein the compound claims and the method of treatment claims of the instant application are anticipated.

25 Applicant’s arguments with respect to claims 1 and 58-89 have been considered but are moot in view of the new grounds of rejection.

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Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines 5 operated by Group 1600 are (703) 308-4556 and 703-305-3592.

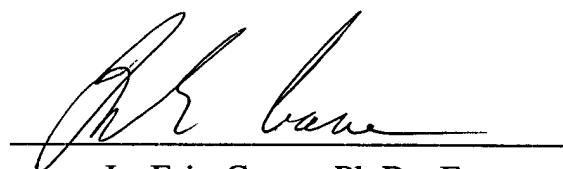
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through 10 Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Johann Richter, can be reached at (703)-308-4532.

Any inquiry of a general nature or relating to the status of this 15 application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235.

LECrane:lec  
08/23/02

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